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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,998	09/14/2000	Michael Berthon Jones	3869/10	8889
7590	12/10/2003		EXAMINER	
Gottlieb Rackman & Reisman P C 270 Madison Ave New York, NY 10016			WEISS JR, JOSEPH FRANCIS	
			ART UNIT	PAPER NUMBER
			3743	18
DATE MAILED: 12/10/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/661,998	JONES, MICHAEL BERTHON
	Examiner	Art Unit
	Joseph F Weiss Jr.	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 September 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-48 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10, 12-15 and 17-48 is/are rejected.
- 7) Claim(s) 11 & 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION
Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 2, 18, 34 & 38, 47-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The written description does not describe a method/device with a sensor external the circuit so that it is independent of leaks/make a ventilator with such positioning nor an type of sensor that is "leak independent" in terms of explaining what is meant by being "leak independent."

3. Claims 47-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. How to position the sensor external the circuit so that it is independent of leaks/make a ventilator with such positioning, nor an type of sensor that is "leak independent" in terms of explaining what is meant by being "leak independent."

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-2, 9-10, 17-34 & 37-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Banner et al (US 6390091).

In regards to claims 1, 17, 33 & 37, Banner discloses an apparatus/method for providing synchronized ventilatory support to a patient comprising at least one sensor to generate a respiratory effort signal (100) that is a "respiratory effort sensor" positioned to be independent of leaks, at least one sensor to generate a respiratory air flow signal (90); a processor for analyzing both respiratory air flow and the effort signal (60/62) which is fully capable of and does determine the instantaneous respiratory phase of a patient (note the incremental management assessment of WOB methodology Fig 7 & supporting text) and generates a pressure request signal as a function of said instant phase and a ventilation pressure amplitude (see generally figs 3-8 and supporting text and & Figs 11-12 and supporting text) and hence has sufficient configuration by dint of

having the function/capability and a servo-controlled blower (20) to provide pressurized air to a patient in accordance with the pressure request signal.

In regards to claim 2, 18, 34 & 38, Banner discloses the use of an esophageal pressure effort sensor (100, see fig 10) which are fully capable of being operated to be "independent of leaks in airflow."

In regards to claim 9 & 25, Banner discloses delivering ventilation with a maximum and non-zero minimum value range (Col. 7 line 65 to the end of the col) which is indicative of pressure amplitudes (note correlation of work of breathing values to pressure and flow)

In regards to claim 10 & 26, Banner discloses the calculation/generation of a desired pressure request signal, including an error value that is a function of a difference between calculated/sensed ventilation and desired to targeted ventilation. (See col. 5 lines 15-27)

In regards to claims 19-32 & 39-40, the processor of Banner is fully capable of evaluating fuzzy inference rules related to various signals that are indicative of different aspects and parameters of pressure and ventilation in order to operate and control the system in response to the pulmonary needs of a user.

In regards to claims 27 & 32, while being parallel to the indefinite claims 11 & 16 have been rejected purely based upon the fact that in interpreting the claims the language present in these apparatus claims that parallels the indefinite language of claims 11 & 16 does not positively recite any structure or function or intended result or use or purpose that bring in by implication any structure, but merely present rules that any processor could evaluate, accordingly they can be rejected because they are not positive recitations that further limit the invention.

In regards to claims 41 & 42, Banner discloses a device that practices a commensurate method wherein the instantaneous respiratory breathing phase is a fraction of the complete respiratory cycle. (Note figs 8-9 and supporting text).

In regards to claims 43-46, Banner discloses the use of a mask/tube arrangement for use with the device (Col. 8 lines 16-32).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-8, 11-16 and 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banner in view of Schmidt (US 6186142).

In regards to claims 3-8, 12-15, 35-36, Banner substantially discloses the instant application's claimed invention to include the utilization of standard rules/algorithms in an "if--then" format (see figs 3-7 & 11-12) for evaluating respiratory signals, but does not explicitly disclose utilizing Fuzzy logic to evaluate respiratory signals. However, Schmidt disclose such (See figs 3-4, note col. 12 line 50-col. 13 line 60, specifically col. 12 lines 52-55). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Schmidt and used them with the device of Banner. The suggestion/motivation for doing so would have been because standard algorithmic if --then formats are

interchangeable with fuzzy logic algorithmic formats (See Schmidt col. 12 lines 52-55). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banner in view of Sipin (US 4957107).

In regards to claims 47-48, substantially discloses the instant application's claimed invention, but does not explicitly disclose use of an external sensor. However, Sipin disclose such (40/41). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Sipin and used them with the device of Banner. The suggestion/motivation for doing so would have been to permit direct access to the sensor for calibration, repair/replacement. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Allowable Subject Matter

4. Claims 11 & 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

5. Applicant's arguments filed 26 Sep 03 have been fully considered but they are not persuasive.

In regards to the 35 USC 112 rejections, applicant's amendments are proper and responsive and resolve the issues, therefore the rejections are withdrawn. (This determination was made exclusive of applicant's arguments/comments on the issues of the rejection/issue)

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regards to the 35 USC 102 & 103 rejections, applicant's amendment is proper and responsive, but does not resolve the rejection, there the rejections are retained.

Regarding applicant's assertion that Banner does not determine "phases of respiratory cycle" it is noted that applicant's manner of phasing is merely to place an artificial methodological gloss over the phenomenon of mammalian respiration and call the actions applicant takes at different artificial designations of "phase" to take certain actions, all methods that manage respiration do this and expressly related to the methodology of Banner, this is done as reflected in Fig 7 and its supporting text.

In regards to the ability of Banner to change pressure support levels applicant is correct “as long as the patient maintains an inspiratory effort, airway pressure is held constant at the pre-selected pressure support ventilation level” but why fix something that is not broken, its when the person does not maintain proper inspiratory effort that Banner’s device takes action, regardless of respiratory cycle, why? Because the person needs to breath NOW, not correction for the next breath that may not be coming if you don’t take action NOW. The examiner quotes the abstract of Banner “and the pressure and/or flow rate is CONTROLLED throughout the inspiratory phase to provide a pressure support level that provides the desired work of breathing in the patient.” I.e as the person breaths in, if its not sufficient actions are taken to control pressure/flow actively in real time to insure the person then meets the WOB range/zone, this inherently is synchronization. Applicant’s selective citation and biased characterization of the reference are not persuasive, references are read in their entirety in order to determine what the invention is that the prior art discloses.

“New” method’s of claims 47-48 are addressed in the rejection.

Regarding applicant’s assertion that Banner does not disclose an “esophageal pressure effort sensor.” Applicant discloses such as being “a pressure transducer implanted in the chest.” (Page 10 lines 12-18 of written description). Banner discloses a pressure sensor that is implanted in the chest. No additional structural differences/distinctions attach to the pressure transducer when the label “esophageal” is used to set forth the transducer. Hence the reference meets the limitations as set forth by applicant.

Furthermore, placing a pressure sensor upon the species of catheter in no way alters what it is, a pressure sensor is empirically a pressure sensor, and placement/labeling it as an endo-tracheal pressure sensor does nothing to distinguish it

Art Unit: 3743

from using the label "esophageal pressure effort sensor" Also, it is noted that an endotracheal tube as merely a catheter is fully capable of passing into the esophagus thus delivering the sensor to this environment to measure pressure there instead of in the trachea.

In response to applicant's arguments, the recitation "leak independent" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

In response to applicant's argument that "leak independence of the sensors" , a recitation of the intended use/results of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The examiner speculates that what applicant means by leak independence and the labels he is placing on a garden variety pressure sensor is that it is being physically implanted into the tissue of the user? If that is what applicant means, then the examiner recommends that applicant claim it that way, while claims are read in light of the written description, limitations in the written description are not read into the claims. If applicant

Art Unit: 3743

claims the elements of his invention in a broad nebulous manner then more art is eligible as prior art that can be read upon the invention. Arguments cannot remedy the problems that this form of claiming generates during prosecution, only actual amendments to the claims that are in accord with the written description and the invention can remedy this problem.

In response to applicant's argument that representing respiratory effort as a "fraction of a revolution" , a recitation of the intended use/results of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that "processor evaluates fuzzy inference rules" , a recitation of the intended use/results of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant is not positively claiming a microprocessor programmed with applicant's fuzzy logic rules. Usage of the term configuration does not result in converted intended results into structure, the term "programmed" does. If applicant as current, legally binding precedent on the term "configured" as positive claiming please

disclose it for evaluation and entry into the file, otherwise the PTO policy in terms of positive claiming of algorithms to lend structure is to claim the processor as "programmed" with such algorithms. Even if it does, the prior art devices by being fully capable of achieving the same results they are inherently configured to achieve these same results, thus using "configuration" does nothing to distinguish over a prior art reference that has the same capabilities absent a claiming of specific structural features that are patently distinct from the configuration the prior art possesses to achieve this same result.

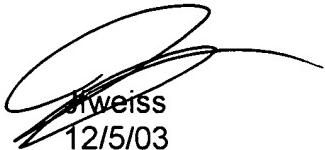
Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5540732, 5271395, 5201808, 4596251.

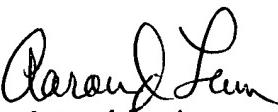
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F Weiss Jr. whose telephone number is 703-305-0323. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703-308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



J. Weiss
12/5/03



Aaron J. Lewis
Primary Examiner